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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,383	10/24/2003	Shalaby W. Shalaby	PC25203A	1654

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,383	SHALABY ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All .b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 15 are pending in this action.

Information Disclosure Statement

It is noted that as of this date, no information disclosure statement is of record in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 4, 6 – 8, 11 – 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection**.

Instant claims are generic with respect to at least one of the following two genuses, neither of which have been sufficiently described in order to show possession of compositions or methods comprising the entire genus. The genuses which have not been sufficiently described are:

1) the pharmaceutical compound, and

2) the functional polymer.

The invention defined by the claims requires a specific type of physiochemical interaction between the pharmaceutical compound and the functional polymer in order to produce the desired result. With regard to the pharmaceutical compound, the aryl-heterocyclic compounds described in US 4,831,031 (incorporated by reference into instant disclosure on page 3 of the specification) are sufficiently similar in structure or function that the showing of ziprasidone is sufficient to show possession of this sub-genus. However, this showing is not sufficient to show possession of all pharmaceutical compounds, or all aryl-heterocyclic pharmaceutical compounds. The genus of pharmaceutical compounds, and the sub-genus of aryl-heterocyclic pharmaceutical compounds, includes materials having disparate functions and properties. These materials may be hydrophilic or hydrophobic; they may be anionic, cationic, zwitterionic, or neutral; they may have one or more of a multitude of biological functions. Clearly, the showing in the specification, which is limited to ziprasidone, is not sufficient to show possession of all such materials in the context of the invention.

Furthermore, the generic functional polymer lacks sufficient description. The disclosure describes only the functional polymers recited in claim 3. These species relate to a special subset of functional polymers all of which are recognized in the art as having similar functions in pharmaceutical systems in that they are known to provide for controlled release of drugs. These polymers operate in the same fashion in that they can be manipulated by copolymerization, end-group manipulation, or blending in order to control the degradation rate of the polymer and thus the release rate of a drug that is associated therewith. This disclosure is not commensurate in scope with the genus of

functionalized polymers, which includes a large variety of polymers with a diverse set of physical and chemical properties. Functionalized polymers may be bioabsorbable or non-bioabsorbable, erodable or non-erodable, natural or synthetic, hydrophilic or hydrophobic, neutral or cationic or anionic, they may contain one or more of a wide variety of functionalities, including carboxylate, thiol, sulphonate, phosphate, alcohol, ketone, aldehyde, ester, ether, amine, ammonium, and so forth. Clearly, the limited disclosure of polymers having very specific chemical and physical properties is not sufficient to show possession of all functionalized polymers in the context of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 4 – 7 are rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by US 6,232,304 to Kim et al.

Kim discloses an ionic conjugate of ziprasidone and a cyclodextrin (abstract, examples). Cyclodextrin reads on a "functionalized polymer". The free base form of ziprasidone is poorly soluble in water, but the solubility is increased upon forming the

conjugate, meeting the requirements of claim 1 (see table 1, first entry – HPBCD and SBECD are types of cyclodextrins). Ziprasidone reads on the pharmaceutical compounds of claims 2, 4, and 5. The conjugate is taught to be stored in a lyophilized form, but then redissolved in water for use as an injectable (example 2), reading on the pharmaceutically acceptable vehicle of claim 6. Claim 7 recites an intended use ("for controlled release or immediate release"), which is not afforded patentable weight in a composition claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 8 and 11 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,232,304 to Kim et al. in view of US 5,916,883 to Shalaby et al.

Some of the teachings of Kim are discussed above. Note that the teachings of ziprasidone in Kim read on the pharmaceutical compounds of claims 12 – 14. The teaching of lyophilization reads on distillation under reduced pressure.

What is lacking is a teaching of the polymers of claims 3 and 8, and a teaching to use an organic solvent as required by claim 11.

Shalaby teaches cyclodextrin derivatives. The derivatives have polymers such as polylactide, polyglycolide and polycapralactone grafted onto them (table II, examples 1 and 2). Shalaby calls these materials acylated beta cyclodextrin conjugates (ACDs); they read on the polymers of claims 3 and 8. These polymers are suggested for use in forming an ionic conjugate with drugs having ionizable (ionigenic) amines (col. 1, line 60 – col. 3 – 23). The use of this cyclodextrin derivative is advantageous because it effects controlled release of the drug (example 5 and table V). The method of making the drug-polymer conjugate in Shalaby is similar to that of Kim, except that acetone, an organic solvent, is used instead of water to dissolve the drug and ACD (example 3), reading on the "organic solvent" of claim 11.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the ACD's of Shalaby and also to use the organic solvent acetone in the invention of Kim. The motivation comes from Shalaby's teaching that a controlled release of active agent can be effected by using the derivatised cyclodextrins, which the artisan would recognize as an improvement over Kim's teachings. Since

acetone is suggested for use instead of water with the ACD's, the artisan would be merely following the suggestion of the art by using an organic solvent.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,232,304 to Kim in view of US 3,418,329 to Robert et al.

The teachings of Kim are discussed above. What is lacking is the teaching of using vegetable oil as a carrier.

Robert teaches that in the art of parenteral carriers, water and vegetable oil are considered equivalents, both useful for the same purpose (col. 3, lines 25 – 26).

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use vegetable oil instead of water as the carrier in the invention of Kim. It is generally obvious to substitute art-recognized equivalents, and the artisan would expect a reasonable expectation of success in doing so.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,232,304 to Kim et al. in view of US 5,916,883 to Shalaby et al and US 3,418,329 to Roberts et al.

The teachings of these references have been discussed above.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use vegetable oil instead of water as the carrier in the invention of Kim and Shalaby. It is generally obvious to substitute art-recognized equivalents, and the artisan would expect a reasonable expectation of success in doing so.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600